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**EDUCATION**

1978 - 1981      Medical :      Ohio State University, Columbus, Ohio  
   Clerkship Honors - Medicine, Surgery, OB/GYN, Pediatrics  
1974 - 1978      Undergraduate: Biology, BA/MS, Northwestern University, Evanston, Illinois  
   Honors: Biology Combined BA/MS Program

**TRAINING**

1984 -1986      Residency:      Rush-Presbyterian-St. Luke's Medical Center, Cardiology, Chicago,  
   Illinois  
1981 - 1984      Fellowship:      Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois  
   Internal Medicine

**MEDICAL EXPERIENCE**

2001 - Present      Associate Professor of Medicine and Director of Preventive Cardiology, Rush  
   Presbyterian-St. Luke's Medical School, Chicago, Illinois  
1998 - Present      Executive Medical Director, Radiant Research Chicago  
   (Formerly Protocare Trials Chicago Center for Clinical Research)  
1996 - Present      President & CEO Radiant Research Chicago, Chicago, Illinois  
   (Formerly Protocare Trials Chicago Center for Clinical Research)  
1986 - Present      Academic Appointment, Assistant Professor, Department of Medicine, Rush  
   Presbyterian-St. Luke's Medical Center Chicago, Illinois  
1986 - 1996      Medical Director, Chicago Center for Clinical Research Chicago, Illinois

**CERTIFICATION AND LICENSURE**

1987      Cardiology  
1984      Internal Medicine

Licensure:      State of Illinois Physician and Surgeon  
   Number: 036-065126  
   Expiration Date: July 31, 2005

**PATENT/TRADEMARK**

United States Patent Number:    5,279,540 - Michael H. Davidson, M. D., F.A.C.C.  
Date of Patent:    January 18, 1994

Abstract: A method for reducing the risk of atherosclerosis in a patient at risk of same comprising the steps of removing cholesterol ester transfer protein from blood of the patient to reduce the plasma CETP levels in the patient. In an embodiment, the method includes the step of passing the patient's plasma through an apheresis machine to remove at least some of the plasma cholesterol ester transfer

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protein.

## PUBLICATIONS

1. Maki KC, Dicklin MR, Cyrowski MS, Umporowicz DM, Nagata Y, Moon G, Forusz S, **Davidson MH**. Improved calcium absorption from a newly formulated beverage compared with a calcium carbonate tablet. *Nutr Res*. 2002;1163-76.
2. **Davidson MH**. Unidentified multiple risk factor patients: A missed opportunity for primary CHD prevention. *Family Practice Recertification*. 2002;86:23-32.
3. **Davidson, MH**. Controversy surrounding the safety of cerivastatin. *Expert Opin Drug Saf*. 2002; 2:207-12.
4. Maki KC, Dicklin MR, Cyrowski M, Umporowicz DM, Nagata Y, Moon G, Forusz S, **Davidson MH**. Improved calcium absorption from a newly formulated beverage compared with a calcium carbonate tablet. *Nutr Res*. 2002;22: 1163-76.
5. **Davidson MH**, Maki KC, Umprowicz DM, Ingram KA, Dicklin MR, Schaefer E, Lane RW, McNamara JR, Ribabya-Mercado JD, Perrone G, Robins SJ, Franke WC. Safety and tolerability of esterified phytosterols administered in reduced-fat spread and salad dressing to healthy adult men and women. *J Am Coll Nutr*. 2001;20:307-19.
6. **Davidson MH**, Toth P, Weiss S, McKenney J, Hunninghake D, Isaacsohn J, Donovan JM, Burke SK. Low-dose combination therapy with colesvelam hydrochloride and lovastatin effectively decreases low-density lipoprotein cholesterol in patients with primary hypercholesterolemia. *Clin Cardiol*. 2001;24:467-474.
7. Insull W, Toth P, Mullican W, Hunninghake D, Burke S, Donovan JM, **Davidson MH**. Effectiveness of colesvelam hydrochloride in decreasing LDL cholesterol in patients with primary hypercholesterolemia: a 24-week randomized controlled trial. *Mayo Clin Proc*. 2001;76:971-982.
8. Hunninghake D, Insull W, Knopp R, **Davidson M**, Lohrbauer L, Jones P, Kafonek S. Comparison of efficacy of Atorvastatin versus Cerivastatin in primary hypercholesterolemia. *Am J Cardiol*. 2001;88:635-639.
9. **Davidson MH**. Treatment of the elderly with 3-hydroxy-3 methylglutaryl coenzyme A reductase inhibitors: Focus on drug interactions. *J Cardiovasc Pharmacol Therapeut*. 2001;6:219-229.
10. **Davidson MH**, Maki KC, Karp SK, Ingram KA. Management of hypercholesterolemia in postmenopausal women. *Drugs Aging*. 2001;in press.
11. Illingworth DR, Crouse JR 3rd, Hunninghake DB, **Davidson MH**, Escobar ID, Stalenhoef Paragh G, Ma PT, Liu M, Melino MR, O'Grady L, Mercuri M, Mitchel YB. A comparison of simvastatin and atorvastatin up to maximal recommended in a large multicenter randomized clinical trial. *Curr Med Res Opin*. 2001;17:43-50.
12. Insull W Jr, Koren M, Davignon J, Sprecher D, Schrott H, Keilson LM, Brown AS, Dujovne CA, **Davidson MH**, McLain R, Heinonen T. Efficacy and short-term safety of a new ACAT inhibitor, avasimibe, on lipids, lipoproteins, and apolipoproteins, in patients with combined hyperlipidemia. *Atherosclerosis*. 2001;157:137-44.

Revised 5/21/2003

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PM3006736929

13. Raggi, P, Callister, TQ, **Davidson, MH**, Welty, FK, Bachmann, GA, Laskey, R, Pittman, D, Kafonek, S, Scott, R: Aggressive versus moderate lipid-lowering therapy in postmenopausal women with hypercholesterolemia: Rationale and design of the beyond endorsed lipid lowering with EBT scanning (BELLES) trial. *Am Heart J.* 2001;141:722-6.
14. Knapp HK, Schrott H, Ma P, Knopp R, Chin B, Gaziano JM, Donovan JM, Burke SK, **Davidson MH**. Efficacy and safety of combination simvastatin and colesvelam in patients with primary hypercholesterolemia. *Am J Med.* 2001;110:352-360.
15. Dujovne CA, Bays H, **Davidson MH**, Knopp R, Hunninghake DB, Stein EA, Goldberg AC, Jones P, Lipka LJ, Cuffie-Johnson C. Reduction of LDL cholesterol in patients with primary hypercholesterolemia by SCH 48461: results of a multicenter dose-ranging study. *J Clin Pharmacol.* 2001;41:70-78.
16. **Davidson MH**, Maki KC, Dicklin MR. Benefits of new, non-systemic lipid lowering agent: the clinician's perspective. *Preventive Cardiol.* 2001;4:38-39.
17. **Davidson MH**, Kurlandsky SB, Klempell RM, Maki KC. Lipid management in the elderly. *Preventive Cardiol.* 2001;in press.
18. **Davidson MH**. Safety profiles of the HMG-CoA reductase inhibitors: treatment and trust. *Drugs.* 2001;61:197-206.
19. **Davidson MH**. Statin trials in progress: unanswered questions. *Current Atheroscler Rep.* 2001;3:9-13.
20. Maki KC, **Davidson MH**, Umporowicz DM, Schaefer EJ, Dicklin MR, Ingram KA. Lipid responses to plant sterol-enriched reduced-fat spreads incorporated into a NCEP Step 1 diet. *Am J Clin Nutr.* 2001;74:33-43.
21. Ose L, **Davidson MH**, Stein EA, Kastelein JJP, Scott RS, Hunninghake DB, Campodonico S, Insull W, Escobar ID, Schrott HG, Stepanavage ME, Wu M, Tate AC, Melino MR, Mercuri M, Mitchel YB. Lipid-altering efficacy and safety of simvastatin 80mg/day: worldwide long-term experience in patients with hypercholesterolemia. *Clin Cardiol.* 2000;23:39-46.
22. Maki KC, **Davidson MH**. Lean red meat and lean white meat in the NCEP Step I diet. *Curr Treat Options Cardiovasc Med.* 2000;2:7-12.
23. **Davidson MH**, Maki KC, Marx P, Maki AC, Cyrowski MS, Nanavati N, Arce JC. Effects of continuous estrogen and estrogen-progestin replacement regimens on cardiovascular risk markers in postmenopausal women. *Arch Intern Med.* 2000;160:3315-3325.
24. **Davidson MH**, Dicklin MR, Maki KC, Klempell RM. Colesevelam hydrochloride: a non-absorbed, polymeric cholesterol-lowering agent. *Expert Opin Investig Drugs.* 2000;9:2663-2671.
25. Anderson JW, **Davidson MH**, Blonde L, Brown WV, Howard WJ, Ginsberg H, Allgood LD, Weingand KW. Long-term cholesterol-lowering effects of psyllium as an adjunct to diet therapy in the treatment of hypercholesterolemia. *Am J Clin Nutr.* 2000;71:1433-1438.
26. Dobs AS, Schrott H, **Davidson MH**, Bays H, Stein EA, Kush D, Wu M, Mitchell Y, Illingworth RD. Effects of high-dose simvastatin on adrenal and gonadal steroidogenesis in men with hypercholesterolemia. *Metabolism.* 2000;49:1234-1238.

27. Stein E, Plotkin D, Bays H, **Davidson MH**, Dujovne C, Korenman S, Stepanavage M, Mercuri M. Effect of simvastatin (40 and 80 mg/day) in patients with mixed hyperlipidemia. *Am J Cardiol*. 2000;86:406-411.
28. Kastelein JJ, Isaacsohn JL, Ose L, Hunninghake DB, Frohlich J, **Davidson MH**, Habib R, Dujovne CA, Crouse JR, Liu M, Melino MR, O'Grady L, Mercuri M, Mitchel YB. Comparison of effects of simvastatin versus atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-I levels. *Am J Cardiol*. 2000;86:221-223.
29. Maki KC, **Davidson MH**, Marx P, Cyrowski M, Maki AC. Association between elevated plasma fibrinogen and the small, dense low density lipoprotein phenotype among postmenopausal women. *Am J Cardiol*. 2000;85:451-456.
30. Maki KC, **Davidson MH**, O'Mullane J, Daggy BP, Albrecht HH. High-molecular-weight hydroxypropylmethylcellulose (HPMC) taken with or between meals has hypocholesterolemic effects in adult men. *J Nutr*. 2000;130:1705-10.
31. Hunninghake D, Maki KC, Kwiterovich PO, **Davidson MH**, Dicklin MR, Kafonek S. Incorporation of lean red meat into a national cholesterol education program step I diet: a long-term, randomized clinical trial in free-living persons with hypercholesterolemia. *J Am Coll Nutr*. 2000;19:351-360.
32. **Davidson MH**. Does differing metabolism by cytochrome P450 have clinical importance? *Curr Atheroscler Rep*. 2000;1:14-19.
33. Maki KC, **Davidson MH**, Cyrowski M, Maki AC, Marx P. Low density lipoprotein subclass pattern B amplifies adiposity-associated dyslipidemia in postmenopausal women. *J Am Coll Nutr*. 2000;19:23-30.
34. Isaacsohn J, **Davidson MH**, Hunninghake DB, Singer R, McLain R, Black DM. Aggressive lipid lowering initiation abates new cardiac events (ALLIANCE) – rationale and design of atorvastatin versus usual care in hypercholesterolemic patients with coronary artery disease. *Am J Cardiol*. 2000; 86:250-252.
35. **Davidson MH**. Efficacy of antiobesity therapies. *Am J Clin Nutr*. 2000;71:844.
36. **Davidson MH**, Dillon MA, Gordon B, Jones P, Samuels J, Weiss S, Isaacsohn J, Toth P, Burke SK. Colesevelam hydrochloride (cholestagel): a new, potent bile acid sequestrant associated with a low incidence of gastrointestinal side effects. *Arch Intern Med*. 1999;159:1893-900.
37. Maki KC, **Davidson MH**, Malik KC, Albrecht HH, O'Mullane J, Daggy BP. Cholesterol lowering with high-viscosity hydroxypropylmethylcellulose. *Am J Cardiol*. 1999;84:1198-1203.
38. Hays JT, Schroeder DR, Croghan IT, Offord KP, Hurt RD, Wolter TD, Nides MA, **Davidson MH**. Over-the-counter 22 mg nicotine patch therapy for smoking cessation: results from randomized, double-blind, placebo-controlled and open label trials. *Am J Pub Health*. 1999;89:1701-1707.
39. **Davidson MH**, Maki KC. Effects of dietary inulin on serum lipids. *J Nutr*. 1999;129:1474S-7S.
40. Knopp RH, Superko HR, **Davidson MH**, Insull W, Dujovne CA, Kwiterovich PO, Zavoral JH,

- Graham K, O'Connor RR, Edelman DA. Long-term blood cholesterol-lowering effects of a dietary fiber supplement. *Am J Preventive Med.* 1999;17:18-23.
41. **Davidson MH**, Hunninghake D, Maki KC, Kwiterovich PO, Kafonek S. Comparison of the effects of lean red meat vs lean white meat on serum lipid levels among free-living persons with hypercholesterolemia: a long-term, randomized clinical trial. *Arch Intern Med.* 1999;159:1331-8.
  42. Schwartz JL, Chan CC, Mukhopadhyay S, McBride KJ, Jones TM, Adcock S, Moritz C, Hedges J, Grasing K, Dobratz D, Cohen RA, **Davidson MH**, Bachmann KA, Gertz BJ. Cyclooxygenase-2 inhibition by rofecoxib reverses naturally occurring fever in humans. *Clin Pharmacol Ther.* 1999;65:653-60.
  43. **Davidson MH**, Hauptman J, DiGirolamo M, Foreyt JP, Halsted CH, Heber D, Heimburger DC, Lucas CP, Robbins DC, Chung J, Heymsfield SB. Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat: a randomized controlled trial. *JAMA.* 1999;281:235-42.
  44. Stein EA, Illingworth DR, Kwiterovich PO Jr, Liacouras CA, Siimes MA, Jacobson MS, Brewster TG, Hopkins P, **Davidson MH**, Graham K, Arensman F, Knopp RH, Dujovne C, Williams CL, Isaacson JL, Jacobsen CA, Lazkarzewski PM, Ames S, Gormley GJ. Efficacy and safety of lovastatin in adolescent males with heterozygous familial hypercholesterolemia: a randomized controlled trial. *JAMA.* 1999;281:137-44.
  45. Elam MB, Heckman J, Crouse JR, Hunninghake DB, Herd JA, **Davidson MH**, Gordon IL, Bortey EB, Forbes WP. Effect of the novel antiplatelet agent cilostazol on plasma lipoproteins in patients with intermittent claudication. *Arterioscler Thromb Vasc Biol.* 1998;18:1942-7.
  46. Money SR, Herd JA, Isaacsohn JL, **Davidson MH**, Cutler B, Heckman J, Forbes WP. Effect of cilostazol on walking distances in patients with intermittent claudication caused by peripheral vascular disease. *J Vasc Surg.* 1998;267-275.
  47. **Davidson MH**, Epstein M, Burt R, Schaefer C, Whitworth G, McDonald A. Efficacy and safety of an over-the-counter transdermal nicotine patch as an aid for smoking cessation. *Arch Fam Med.* 1998;7:569-74.
  48. **Davidson MH**, Dugan LD, Stocki J, Dicklin MR, Maki K, Coletta F, Cotter R, McLeod M, Hoersten K. A low-viscosity soluble-fiber fruit juice supplement fails to lower cholesterol in hypercholesterolemic men and women. *J Nutr.* 1998;128:1927-32.
  49. Stein EA, **Davidson MH**, Dobs AS, Schrott H, Dujovne CA, Bays H, Weiss SR, Melino MR, Stepanavage ME, Mitchel YB. Efficacy and safety of simvastatin 80 mg/day in hypercholesterolemic patients. *Am J Cardiol.* 1998;82:311-6.
  50. Koren MJ, Smith DG, Hunninghake DB, **Davidson MH**, McKenney JM, Weiss SR, Schrott HG, Henley RW, Tresh P, McLain RW, Bakker-Arkema RG, Black DM. The cost of reaching national cholesterol education panel (NCEP) goals in hypercholesterolaemic patients. A comparison of atorvastatin, simvastatin, lovastatin and fluvastatin. *Pharmacoeconomics.* 1998;14:59-70.
  51. **Davidson MH**, Maki KC, Kong JC, Dugan LD, Torri SA, Hall HA, Drennan KB, Anderson SM, Fulgoni VL, Saldanha LG, Olson BH. Long-term effects of consuming psyllium seed husk on serum lipids in subjects with hypercholesterolemia. *Am J Clin Nutr.* 1998;67:367-76.

52. **Davidson MH**, Maki KC, Synecki C, Torri SA, Drennan KB. Effects of dietary inulin on serum lipids in men and women with hypercholesterolemia. *Nutr Res.* 1998;1:503-17.
53. **Davidson MH**, Maki KC. Conjugate equine estrogens and coronary heart disease risk: serum lipid effects. *Menopause Review.* 1998.
54. Knopp RH, Alagona P, **Davidson MH**, Goldberg AC, Kafonek SD, Kashyap M, Sprecher D, Superko HR, Jenkins S, Marcovina S. Equivalent efficacy of a time-release form of Niacin (Niaspan) given once-a-night versus plain Niacin in the management of hyperlipidemia. *Metabolism.* 1998;47:1097-1104.
55. Maki KC, Kritsch K, Foley S, Soneru I, **Davidson MH**. Age-dependence of the relationship between adiposity and serum low density lipoprotein cholesterol in men. *J Am Coll Nutr.* 1997;16:578-83.
56. **Davidson MH**, Nawrocki JW, Weiss SR, Schwartz SL, Lupien PJ, Jones PH, Haber HE, Black DM. Effectiveness of atorvastatin for reducing low-density lipoprotein cholesterol to national cholesterol education program treatment goals. *Am J Cardiol.* 1997;80:347-8.
57. **Davidson MH**, Testolin LM, Maki KC, Duvillard S, Drennan KB. A comparison of estrogen replacement, pravastatin, or combined therapy for the management of hypercholesterolemia in postmenopausal women. *Arch. Intern Med.* 1997;157:1186-92.
58. **Davidson MH**, Maki KC, Kalkowski J, Schaefer EJ, Torri SA, Drennan KB. Effects of docosahexaenoic acid on serum lipoproteins in patients with combined hyperlipidemia: A randomized, double-blind, placebo-controlled trial. *J Am Coll Nutr.* 1997;16:236-243.
59. **Davidson MH**, Macarlola-Coad J, Maki KC, Hall H. Separate and joint effects of marine oils and simvastatin in patients with combined hyperlipidemia. *Am J Cardiol.* 1997;80:797-798.
60. **Davidson MH**, McKenney J, Stein E, Schrott H, Bakker-Arkema R, Fayyad R, Black D. Comparison of one-year efficacy and safety of atorvastatin versus lovastatin in primary hypercholesterolemia. *Am J Cardiol.* 1997;79:1475-81.
61. Maki KC, Kritsch K, Foley S, Soneru I, **Davidson MH**. Age-dependence of the relationship between adiposity and serum low density lipoprotein cholesterol in men. *J Am Coll Nutr.* 1997;16:578-83.
62. **Davidson MH**, Stein E A, Dujovne CA, Hunninghake DB, Weiss SR, Knopp RH, Illingworth DR, Mitchel YB, Melino MR, Zupkis RV, Dobrinska MR, Amin RD, Tobert JA. The efficacy and six-week tolerability of simvastatin 80 and 160 mg/day. *Am J Cardiol.* 1997;79:38-42.
63. Schlagheck TG, Kesler JM, Jones MB, Zorich NL, Dugan LD, **Davidson MH**, Peters JC. Olestra's effect on vitamin D and E in humans can be offset by increasing dietary levels of these vitamins. *J Nutr.* 1997;127:1666S-85S.
64. Maki KC, **Davidson MH**, McDonald A, Malik KC. Fiber intake and risk of developing non-insulin-dependent diabetes mellitus. *JAMA.* 1997;277:1761-2.
65. **Davidson MH**, Kong JC, Drennan KB, Story K, Anderson GH. Efficacy of the national cholesterol education program step 1 diet. A randomized trial incorporating quick-service foods.

- Arch Intern Med.* 1996;156:305-12.
66. **Davidson MH**, Dugan LD, Burns JH, Sugimoto D, Story K, Drennan K. A psyllium-enriched cereal for the treatment of hypercholesterolemia in children: a controlled, double-blind, crossover study. *Am J Clin Nutr.* 1996;63:96-102.
67. **Davidson MH**. Food additive approvals: risks vs benefits. *Regul Toxicol Pharmacol.* 1996;23:S25-S26.
68. Stein E A, **Davidson MH**, Dujovne CA, Hunninghake DB, Goldberg RB, Illingworth R, Knopp RH, Miller VT, Frost P, Isaacsohn JL, Mitchel YB, Melino MR, Shapiro D, Tolbert JA. Efficacy and tolerability of low-dose simvastatin and niacin, alone and in combination, in patients with combined hyperlipidemia: a prospective trial. *J Cardiovasc Pharmacol Therapeut.* 1996;1:107-16.
69. Bakker-Arkema RG, **Davidson MH**, Goldstein RJ, Davignon J, Isaacsohn JL, Weiss SR, Keilson LM, Brown WV, Miller VT, Shurziaske LJ, Black DM. Efficacy and safety of a new HMG-CoA reductase inhibitor, atorvastatin, in patients with hypertriglyceridemia. *JAMA.* 1996;275:128-33.
70. Ashraf T, Hay JW, Pitt B, Wittels EH, Crouso J, **Davidson MH**, Furberg CD, Radican L. Cost-effectiveness of pravastatin in secondary prevention of coronary artery disease. *Am J Cardiol.* 1996;78:409-14.
71. Borzelleca JF, Cheney M, **Davidson MH**, Degnan FH, Derfler PS, Forbes AL, Glinsmann W, Heckman JH, Miller SA, Rulis AM, Masten LW. Panel discussion: what in the future of macronutrient substitutes in North America? *Regul Toxicol Pharmacol.* 1996;23:S51-9.
72. Illingworth DR, Stein EA, Knopp RH, Hunninghake DB, **Davidson MH**, Dujovne CA, Miller VT, Tobert JA, Laskarzewski PM, Isaacsohn JL, Bacon SP, Tate AC. A randomized multicenter trial comparing the efficacy of simvastatin and fluvastatin. *J Cardiovasc Pharmacol Therapeut.* 1996;1:23-30.
73. Insull W Jr, **Davidson MH**, Demke DM, Sprecher DL, Schwartz SL, Lupien PJ, Jones PH, Haber HE, Black DM. Reduction of LDL cholesterol by 25% to 60% in patients with patients with primary hypercholesterolemia by atorvastatin, a new HMG-CoA reductase inhibitor. *Arterioscler Thromb Vasc Biol.* 1995;15:678-82.
74. Schrott HG, Stein EA, Dujovne CA, **Davidson MH**, Goris GB, Oliphant TH, Phillips JC, Shawarzyn GG. Enhanced low-density lipoprotein cholesterol reduction and cost-effectiveness by low-dose colestipol plus lovastatin combination therapy. *Am J Cardiol.* 1995;75:34-9.
75. Insull Jr W, **Davidson MH**, Demke DM, Dujovne CA, Eckert SM, Ginsberg D, Goldberg AC, Hodis HN, Hughes TA, Kane JP, Oliphant TH, Pitt WA, Schrott HG, Sprecher DL, Zavoral JH. The effects of colestipol tablets compared with colestipol granules on plasma cholesterol and other lipids in moderately hypercholesterolemic patients. *Atherosclerosis.* 1995;112:223-35.
76. **Davidson MH**. Fluvastatin long-term extension trial (FLUENT): summary of efficacy and safety. *Am J Med.* 1994;96:41S-44S.
77. Dujovne CA, **Davidson MH**. Fluvastatin administration at bedtime versus with the evening meal: a multi-center comparison of bio-availability, safety and efficacy. *Am J Med.* 1994; 96:37S-

40S.

78. Epstein KR, Freedman MA, Gorodeski G-I, Wenger NK, **Davidson MH**. Established cardiovascular disease -- does HRT offer benefits?: *Menopause Management*. 1993;2:10.
79. **Davidson MH**, Rosenson RS, Mazzone T. From diagnosis to treatment: focus on costs, safety, and efficacy of antihyperlipidemic agents. *Hosp Formul*. 1993;28:262-82.
80. **Davidson MH**. Antioxidants and lipid metabolism. Implications for the present and direction for the future. *Am J Cardiol*. 1993;71:32B-36B.
81. Ripsin CM, Keenan JM, Jacobs DR Jr, Elmer PJ, Welch RR, Horn LV, Liu K, Turnbull WH, Thyse FW, Kestin M, Hegsted M, **Davidson MH**, Dugan LD, Demark-Wahnefried W, Beling S. Oat products and lipid lowering: a meta-analysis. *JAMA*. 1992;267:3317-25.
82. Dugan LD, Burns J, **Davidson MH**, Synecki C. Exploring the lipid-lowering effects of oats. *J Cardiopulmonary Rehabil*. 1992;12:164-6.
83. Bagdade JD, Ritter MC, **Davidson MH**, Subbaiah PV. Effect of marine lipids on cholesteryl ester transfer and lipoprotein composition in patients with hypercholesterolemia. *Arteriosclerosis Thromb*. 1992;12:1146-52.
84. **Davidson MH**. Emerging trends in lipid management. *Lipids & Atherogenesis*. 1992;2:1-4.
85. Lands WEM, Libelt B, Morris A, Kramer NC, Prewitt TE, Bowen P, Schmeiser D, **Davidson MH**, Burns JH. Maintenance of lower proportions of (n-6) eicosanoid precursors in phospholipids of human plasma in response to added dietary (n-3) fatty acids. *Biochimica et Biophysica Acta*. 1992;1180:147-62.
86. **Davidson MH**. Lipid-lowering agents: current status, future directions. *The Journal of Myocardial Ischemia*. 1991;3:35.
87. **Davidson MH**, Dugan LD, Burns JH, Bova J, Story K, Drennan KB. The hypocholesterolemic effects of b-glucan in oatmeal and oat bran: a controlled study. *JAMA*. 1991;265:1833-9.
88. **Davidson MH**, Burns J, Subbaiah PV, Conn ME, Drennan KB. Marine oil capsule therapy for the treatment of hyperlipidemia. *Arch Intern Med*. 1991;151:1732-40.
89. **Davidson MH**, Gwynne JT, Khachadurian AK, LaRosa JC, Weber MA, Markowitz JS, Behounek BD. Combination of pravastatin and probucol in the treatment of primary hypercholesterolemia. *Current Science ISSN*. 1991;2:1061-8.
90. **Davidson MH**. The hypocholesterolemic effects of b-glucan in oatmeal and oat bran: a dose controlled study. *JACC*. 1990;15:156 A.
91. **Davidson MH**, Bagdade JD, Liebson PR, Subbaiah P, Messer JV, Schoenberger JA. Comparative effects of marine and olive oil dietary supplementation on coronary risk factors. *Journal of Applied Cardiology*. 1989;4:145-151.
92. Subbaiah PV, **Davidson MH**, Ritter MC, Buchanan W, Bagdade JD. Effects of dietary supplementation with marine lipid concentrate on the plasma lipoprotein composition of hypercholesterolemic patients. *Atherosclerosis*. 1989;79:157-66.



93. **Davidson MH.** Marine oil as a therapy for hyperlipidemia. *Cardiovascular Perspectives.* 1989;4.
94. **Davidson MH, Conn M Preys M Bagdade JD.** 8th 1 ester marine oil capsules to the treatment of type II B hyperlipidemia: a double blind, dose controlled study. *Arteriosclerosis.* 1988;8:592a.
95. **Davidson MH, Liebson PR.** Marine lipids and atherosclerosis: a review. *Cardiovascular Reviews and Reports.* 1986;7:461-72.
96. **Davidson MH, Liebson PR.** Mitral valve prolapse: recent advances in diagnosis and therapy. *Compr Ther.* 1986;12:21-32.

#### ABSTRACTS

1. **Maki KC, Bell M, Oldham KM, Davidson MH.** Is hyperfibrinogenemia a component of the metabolic syndrome? Presented at the American Diabetes Association. December 2001.
2. **Davidson MH, Wheeler A, Rittershaus C, Emmett C, Umporowicz D, Maki KC.** A phase I trial of an immunotherapeutic approach for managing low plasma HDL-C. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September 2001.
3. **Davidson MH, Lukatsko P, Friedhoff L, Sterman A, Walters E, Sun J, Phillips G.** A multi-dose safety, pharmacokinetic and pharmacodynamic study of lovastatin extended-release relative to lovastatin immediate-release. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September 2001.
4. **Davidson M, Scott R, Frohlich J, Cihon F, Kush D, O'Grady L, Vala M, Mitchel Y.** Differential effects of simvastatin and atorvastatin on high density lipoprotein cholesterol and apoprotein A-1 in hypercholesterolemic patients: Cohort and subgroup analyses. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September 2001.
5. **Davidson MH, Hutchinson HG, Chitra R, Raza A, Gotto A.** ZD4522 is superior to atorvastatin in decreasing LDL-C and increasing HDL-C in patients with type IIa and IIb hypercholesterolemia. Submitted to *American College of Cardiology* annual meeting.
6. **Maki KC, Davidson MH, Palmisano J, Susmano A, Dobs A, Kerber I, Hunninghake D, Knopp R, Goldberg A, McKenney J, Kakavas P, Walters D Bittar N.** Separate and combined efforts of hormone replacement and simvastatin 10 mg on lipoprotein (a) and lipoprotein subfractions in postmenopausal women with hypercholesterolemia. Submitted to *American College of Cardiology* annual meeting.
7. **Maki KC, Davidson MH, Cyrowski M, Maki AC, Marx P.** Low density lipoprotein (LDL) subclass pattern B amplifies adiposity-associated dyslipidemia in postmenopausal women. *FASEB, 2000.*
8. **Davidson MH, Maki KC, Marx PD, Arce J-C, Nanavati N.** Effects of low-dose, continuous combined hormone replacement on serum lipids in postmenopausal women. Presented at the *First Conference on Arteriosclerosis, Thrombosis, and Vascular Biology, 2000.*
9. **Maki KC Davidson MH, Marx PD, Cyrowski M, Arce J-C.** Effects of continuous hormone replacement therapy on indicators of carbohydrate metabolism. Presented at the *American Diabetes Association 60<sup>th</sup> Scientific Sessions, 2000.*

10. Maki KC, **Davidson MH**, Susmano A, Maki AC. Low-density lipoprotein subclass pattern B and adiposity-associated dyslipidemia in postmenopausal women. Presented at the *American College of Nutrition* annual meeting, 2000.
11. Maki KC, **Davidson MH**, Tsushima R, Matsuo N, Tokimitsu I, Umporowicz D, Ingram KA, Dicklin MR, Bell M, Anderson BD, Frost SD, Tagala A. Diacylglycerol vs soybean oil in a weight reduction diet. Presented at *North American Association for the Study of Obesity* annual meeting, 2000.
12. **Davidson MH**, Maki KC, Hunninghake DB, Knopp RH, Goldberg RB, Waters D, Dobs AS, Cyrowski M. Effects of Low Dose Simvastatin and Hormone Replacement Therapy on Serum Lipids in Postmenopausal Women with Hypercholesterolemia. *American College of Cardiology 49<sup>th</sup> Annual Scientific Session*, 2000.
13. Maki KC, **Davidson MH**, Cyrowski M, Maki AC, Marx P. Adiposity-associated Dyslipidemia in Postmenopausal Women. Submitted for *Experimental Biology* annual meeting, Apr 15-18, 1999.
14. Maki KC, **Davidson MH**, Umporowicz D, Schaefer E, Dicklin MR, Ingram KA, Chen S, Gebhart B, Franke WC. Lipid Responses to Plant Sterol-enriched Reduced-fat Spreads Incorporated into a Step I Diet. *Circulation*. 1999 Nov;100:I-115.
15. Maki KC, **Davidson MH**, Umporowicz D, Dicklin MR, Ingram KA, Gebhart B, Schaefer E, Chen S, Franke WC. Effects of Plant Sterol-enriched Reduced-fat Spreads on Serum Carotenoid and Fat-Soluble Vitamin Levels. *J Am Coll Nutr*. 1999 Nov;18:536.
16. Maki KC, **Davidson MH**, Marx P, Cyrowski M, Maki AC. Low Density Lipoprotein Subclass Distribution Pattern Does Not Modify Serum Lipid and Apolipoprotein Responses to Hormone Replacement Therapy. 1999 Oct; Proceedings, *9<sup>th</sup> International Menopause Society World Congress on the Menopause*.
17. Maki KC, **Davidson MH**, Cyrowski M, Maki AC. Association Between Elevated Plasma Fibrinogen and the Small, Dense Low Density Lipoprotein Phenotype Among Postmenopausal Women. *Circulation*. 1999 Mar 2;99:1124.
18. Rippe J, Bonovich K, Colfer H, **Davidson MH**, Dujovne C, Fried D, Greenspan M, King S, Karlsberg R, LaForce C, Litt M A Multicenter, Self-Controlled Study of Cholestin<sup>TM</sup> in Subjects with Elevated Cholesterol. *Circulation*. 1999 Mar 2;99:1123.
19. **Davidson MH**, Weeks CE, Lardy H, Maki KC, Umporowicz D. Safety and Endocrine Effects of 3-Acetyl-7-Oxo DHEA. *FASEB*. 1998, Mar 20;12:A764.
20. Heinonen TM, Stein E, Weiss SR, McKenney JM, **Davidson MH**, Shurzinske L, Black DM. The Lipid Lowering Effects of Atorvastatin, a New HMG-CoA Reductase Inhibitor: Results of a Randomized, Double-Masked Study. Submitted to *Clinical Therapeutics*, 1996.
21. **Davidson MH**, Dujovne CA, Hunninghake DB, Goldberg RB, Stein EA, Knopp RH, Illingworth DR, Miller VT, Frost PH, Tobert JA. Efficacy of Low Doses of Simvastatin and Niacin Used Concomitantly in Patients with Combined Hyperlipidemia. Xth International Symposium on Atherosclerosis. Montreal (Canada), October, 1994.
22. Nawrocki J, Weiss S, Sprecher D, **Davidson MH**, Schwartz S, Lupien P, Jones P, Haber H, Black D. Reduction of LDL-C by More Than 60% With the HMG-CoA Reductase Inhibitor

- Atorvastatin. Xth International Symposium on Atherosclerosis. Montreal (Canada), October, 1994.
23. Bakker-Arkema R, **Davidson MH**, Goldstein R, Davignon J, Isaacsohn J, Weiss S, Keilson L, Brown V, Miller V, Shurzinske L. Atorvastatin, a New HMG-CoA Reductase Inhibitor (HMGRI), is Effective and Safe in Hypertriglyceridemic Patients. Xth International Symposium on Atherosclerosis. Montreal (Canada), October, 1994.
  24. LaBelle P, **Davidson MH**, Gazdick L, Liss C. Efficacy of Starting Doses of Simvastatin vs Pravastatin in Elderly and Non-Elderly Patients. Xth International Symposium on Atherosclerosis. Montreal (Canada), October, 1994.
  25. **Davidson MH**, Burns JH, Sugimoto DH MD, Fuerst F, Drennan KB, Troendle AJ. The Comparative Efficacy of Fluvastatin. A New Synthetic HMG-CoA Reductase Inhibitor in Hyperlipidemic Patients Stratified by Genetic Disorder and Gender. XIth International Symposium on Drugs Affecting Lipid Metabolism. Florence (Italy), May, 1992.
  26. Harris WS, **Davidson MH**, Dujovne CA, Nash DT, Cefalu WT. For the Promega Study Group: Long-term Safety Of Fish Oil In Hyperlipidemic Patients: A New Synthetic HMG-CoA Reductase Inhibitor in Hyperlipidemic Patients Stratified by Genetic Disorder and Gender. XIth International Symposium on Drugs Affecting Lipid Metabolism. Florence (Italy), May, 1992.
  27. **Davidson MH**, Dugan LD, Drennan KB, Story K. Combination Marine Oil & Lovastatin Therapy For Familial Combined Hyperlipidemia. Xth International Symposium on Drugs Affecting Lipid Metabolism. Houston, Texas, November, 1989.
  28. **Davidson MH**, Subbaiah PV, Segrest JP, Bagdade JD. Cholesterol and Saturated Fat Content of Fish Oil (FO) Preparations Influences the Hypolipidemic Response in Type IV Hyperlipidemic Patients. American College of Cardiology, Annual Meeting. Atlanta, Georgia, March, 1988.
  29. **Davidson MH**. Safety of Omega-3 Fatty Acids. Submitted to the *American Journal of Clinical Nutrition*. National Meeting, Las Vegas, Nevada, March, 1988.
  30. **Davidson MH**, McKenna R, Sullivan DP, Liebson PR, Schoenberger JA, Messer JV. Bleeding Time Prolongation With Marine Oil in Conjunction With Other Anti-Platelet Agents. American College of Cardiology, Annual Meeting. New Orleans, Louisiana, March, 1987.
  31. **Davidson MH**. Cholesterol Content of Fish Oil. *NEJM*, [Letter to the Editor]. September, 1987.
  32. **Davidson MH**, Liebson PR, Bagdade JD, Messer JV, Schoenberger JA. Marine Lipid Concentrate Reduces Coronary Risk Factors: Double Blind Comparison With Olive Oil. American College of Cardiology, Annual Meeting. Atlanta, Georgia, March, 1986.
  33. **Davidson MH**. Effects of Marine Oil on Blood Lipids. American Academy for the Advancement of Science, Annual Meeting. Philadelphia, Pennsylvania, May, 1986.
  34. **Davidson MH**, Subbaiah PV, Bagdade JD. Favorable Changes In The Factors Affecting Reverse Cholesterol Transport After Feeding Marine Lipids To Hypercholesterolemic (HC) Patients. *Circulation* 1986;74:II, 32.
  35. **Davidson MH**, Billhardt RA. Acute Ventricular Septal Rupture in Myocardial Infarction:

Prognostic Factors for Survival. *Clinical Research* 1985, April.

36. **Davidson MH**, Stang JM. The Clinical Severity of Isolated Disease of the Diagonal Branch Coronary Artery. American Heart Association, National Meeting. Dallas, Texas. November, 1981. American College Physicians, Regional Meeting. Dayton, Ohio, October, 1981.
37. **Davidson MH**, Stang JM. The Efficacy of Floating Telemetry Unit Within an Ambulatory Cardiac Care Unit. APCR, Midwest Regional Meeting. Chicago, Illinois; November, 1981. American College Physicians, Regional Meeting. Dayton, Ohio, October 1981.

#### OTHER PUBLICATIONS

1. **Davidson MH**, Maki KC. Cardiovascular Risk Factors: Evaluation and Treatment Goals. In: **Kris-Etherton PM**, Burns J (eds). *Cardiovascular Nutrition: Strategies and Tools for Disease Management and Prevention*. Chicago, IL: American Dietetic Association, 1998;3-16.
2. McDonald A, Maki KC, **Davidson MH**. Management of Dyslipidemia and Hypertension. In: **Kris-Etherton PM**, Burns J, (eds). *Cardiovascular Nutrition: Strategies and Tools for Disease Management and Prevention*. Chicago, IL: American Dietetic Association, 1998;17-27.

#### PROFESSIONAL ORGANIZATIONS

1998	American Medical Association, Illinois State Medical Society
1991	American College of Cardiology, Fellow
1991	American College of Chest Physicians, Fellow
1986 -1989	Young Physician Section Delegate
1984 -1986	Illinois State Medical Society, Vice Chairman, Resident Section Chairman, Resident Section, American College of Physicians Associate, Chicago Heart Association, American Heart Association - Epidemiology, Associate fellow
1984 - 1985	Alternate Delegate to the House of Delegates, State of Illinois Representative
1983 - 1985	American Medical Association, Resident Selection Delegate

## CLINICAL RESEARCH EXPERIENCE

Since 1986, Dr. Michael H. Davidson has served as Principal Investigator in a vast number of studies in the following areas:

- Hypercholesterolemia
- Claudication
- Food, Nutrition and Diet
- Heart Failure/Myocardial Infarction
- Hypertension
- Obesity
- Diabetes
- Smoking Cessation
- Osteoporosis

The following is a list of selected studies conducted to date:

1. A 4-Year Population-Based, Randomized, Open-Label Study Comparing the Effect of Aggressive Lipid Lowering with XXXXXXX Versus Usual Care in Hypercholesterolemic Patients with Coronary Artery Disease at Risk of Adverse Outcomes. (259)  
Principal Investigator: Michael Davidson, M.D.
2. A Multi-center, Randomized, Double-Blind, Four Arm, Parallel Group Trial to Evaluate the Separate and Combined Effects of XXXXXXXXXXXXXXXX and XXXXXXXXXXXXXXXX. (304)  
Principal Investigator: Michael Davidson, M. D.
3. A Randomized, Double-Blinded, Parallel Group Evaluation of XXXXXXX. (356)  
Principal Investigator: Michael Davidson, M. D.
4. XXXXXXXXXXXXXXXX as Adjunctive Therapy in Subjects with Type 2 Diabetes Mellitus Not Well Controlled on XXXXXXXXXXXXXXXX: A Three-Month Open-Label, Parallel Comparative Trial with Optional One Year Extension. (426 & 426 Ext.)  
Principal Investigator: Michael Davidson, M. D.
5. A Randomized, Double-Blind, Active-Controlled Evaluation of the Dose-Response of XXXX in Patients with Intermittent Claudication. (510)  
Principal Investigator: Michael Davidson, M. D.
6. A Randomized, Double-Blind, Placebo-Controlled, Escalating Dose and Pharmacokinetic Study to Evaluate the Safety of the XXXXXXXXXXXXXXXX. (608)  
Principal Investigator: Michael Davidson, M. D.
7. A Randomized, Double-Blind, Parallel Group Evaluation of XXXXXXXXXXXXXXXX. (650)  
Principal Investigator: Michael Davidson, M. D.
8. The Efficacy and Safety of XXXX for the Treatment of Mild to Moderate Obesity: A Randomized, Double-Blind, Placebo-Controlled Trial. (659)  
Principal Investigator: Michael Davidson, M. D.

9. A Randomized, Double-Blind, Placebo-Controlled Trial of the Effect of XXXXX. (667)  
Principal Investigator: Michael Davidson, M. D.
10. A Randomized Study to Evaluate the Effect of XXXXXXXXXX. (669)  
Principal Investigator: Michael Davidson, M. D.
11. A Multi-center, Randomized, Open-Label, Parallel Study to Evaluate XXXXXXXX. (683)  
Principal Investigator: Michael Davidson, M. D.
12. A Twenty-eight Week, Double-Blind and Observer-Blind to Lipid Values, Active-Controlled, Randomized, Parallel-Group, Multi-center Study to Assess the Safety and Efficacy of XXXXXXXXXX Administered Once Daily at Bedtime in Patients with Primary Hypercholesterolemia Compared to XXXXX. (685)  
Principal Investigator: Michael Davidson, M.D.
13. A Twenty-eight Week, Open-Label, Multi-Center, Extension Study to F351-E00 to Prospectively Evaluate the Long-Term Safety and Efficacy of XXXXXXXX XX Mg Slow Release (SR) Monotherapy in Patients With Primary Hypercholesterolemia (685X)  
Principal Investigator: Michael Davidson, M.D.
14. A Randomized, Double-Blind, Trial of XXXXXXXX vs. Placebo in Patients With Primary Hypercholesterolemia (693)  
Principal Investigator: Michael Davidson, M.D.
15. Phase II Double-Blind, Placebo-Controlled, 4-Week Multiple Dose Evaluation of XXXXX For Its Safety, Toleration and Efficacy for Increasing XXXX in Older Men and Women. (695)  
Principal Investigator: Michael Davidson, M.D.
16. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study Evaluating XXXXXXXX XXXXXXXX Daily for the Treatment of Episodic Heartburn. (701)  
Principal Investigator: Michael Davidson, M.D.
17. A Multiple-Dose Safety, Pharmacokinetic and Pharmacodynamic Study of XXXXX Relative to XXXX  
Principal Investigator: Michael Davidson, M.D.
18. Collection of Normal Human Plasma. (711)  
Principal Investigator: Michael Davidson, M.D.
19. The Efficacy and Safety of XXXXX for the Treatment of Constipation: A Randomized, Double-Blind, Placebo Controlled Pilot Trial. (712)  
Principal Investigator: Michael Davidson, M.D.
20. A Randomized, Double-Blind, Parallel, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy of XXXXX Therapy in Patients with Hypertriglyceridemia. (720)  
Principal Investigator: Michael Davidson, M.D.
21. Randomized, Double-Blind, Placebo-Controlled Re-challenge Test of XXXXX. (722)  
Principal Investigator: Michael Davidson, M.D.
22. Phase I Double-Blind, Placebo-Controlled, Multiple Dose Evaluation of XXXXX, For It's Safety, Toleration and Efficacy in Calorically Restricted Men and Women. (728)

- Principal Investigator: Michael Davidson, M.D.
23. A 1-Year Randomized, Double-Blind, Placebo-Controlled, Multi-center Study Comparing the Efficacy of XX and XX XXXXXXXX in Patients with Peripheral Vascular Disease (740)  
Principal Investigator: Michael Davidson, M.D.
  24. The Effect of LDL-cholesterol Lowering Beyond Currently Recommended Minimum Targets on Coronary Heart Disease (CHD) Recurrence in Patients With Pre-Existing CHD (744)  
Principal Investigator: Michael Davidson, M.D.
  25. A Double-Blind, Randomized Placebo Controlled Trial of Three Doses of XXXXXXXX and XXXXXX for the Prevention of Postmenopausal Osteoporosis. (761)  
Principal Investigator: Michael Davidson, M.D.
  26. Comparison of the Prevalence of Cardiac Valvular Abnormalities in Patients Treated with XXXXXX and XXXX in Combination for at Least Three Consecutive Months Versus Untreated Controls, as Assessed by Echocardiogram. (769)  
Principal Investigator: Michael Davidson, M.D.
  27. A Multi-center, Double-Blind, Completed-Block, 3-Period, Crossover Study to Evaluate the Effect of XXXXXX on Postprandial Hyperlipidemia in Patients with Combined Hyperlipidemia. (800)  
Principal Investigator: Michael Davidson, M.D.
  28. A Long-Term, Open-Label, Multi-Center Trial of the Safety and Efficacy of XXXXXXXX in Patients With Dyslipidemia. (938)  
Principal Investigator: Michael Davidson, M.D.
  29. A Multi-center, Randomized, Parallel Group Study to Evaluate the Effect of Dosing Time on Efficacy and Safety of XXXXXX in Patients with Primary Hypercholesterolemia. (939)  
Principal Investigator: Michael Davidson, M.D.
  30. A Double-Blind, Randomized Comparison of the Efficacy and Safety of 52 Weeks of XXXXXXXX Therapy Plus Diet in the Treatment of Obesity in Peri and Post-Menopausal Women at Cardiovascular Risk (980)  
Principal Investigator: Michael Davidson, M.D.
  31. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXXXXXX XXXXXXXX and XXXXXXXX Alone and in Combination in Patients with Primary Hypercholesterolemia. (993)  
Principal Investigator: Michael Davidson, M.D.
  32. A Pilot Double-Blind, Placebo-Controlled, Randomized Crossover Study of XXXXXX in Patients with Stable Intermittent Claudication. (A112)  
Principal Investigator: Michael Davidson, M.D.
  33. Efficacy and Safety of XXXX compared with Subcutaneous Human Insulin Therapy in Subjects with Type 1 Diabetes Mellitus: A Six-Month, Outpatient, Parallel Comparative Trial (1001)  
Principal Investigator: Michael Davidson, M.D.
  34. A Double-Blind Investigation of the Efficacy and Safety of Morning vs. Evening Dosing of Two Doses of XXXXXX Compared to Placebo in Subjects with Primary Hypercholesterolemia (1034)  
Principal Investigator: Michael Davidson, M.D.

35. A Multicenter, Double-Blind, Randomized, Parallel, 36-Week, Dose Escalation Study to Evaluate the Efficacy and Safety of XXXXXX 40 and 80mg/day Versus XXXXXX 20, 40 and 80mg/day in Patients with Hypercholesterolemia (1058)  
Principal Investigator: Michael Davidson, M.D.
36. A Multicenter Six Week Randomized Open-Label Parallel Arm Study comparing the Efficacy of Once Daily XXXXXX to XXXXXX in Hypercholesterolemic Patients (The Challenge Study). (1061)  
Principal Investigator: Michael Davidson, M.D.
37. A Study to Evaluate the Degree of Correlation Between XXXX Ultrasound, XXXXXX XXXXXX, and XXXXXX as Methods to Detect Potential Fat Infiltration of the Liver Following 80 and 160 mg XXXX, or Placebo dosed Once Daily for 38 Days in Hypercholesterolemic Patients. (1077)  
Principal Investigator: Michael Davidson, M.D.
38. Efficacy and Safety of Inhaled Compared with Subcutaneous Human Insulin Therapy in Subjects with Type 2 Diabetes Mellitus: A Six-Month, Outpatient, Parallel Comparative Trial (1090)  
Principal Investigator: Michael Davidson, M.D.
39. Efficacy and Safety of Inhaled Human Insulin Therapy in Subjects with Type 2 Diabetes Mellitus Not Well Controlled with Combination Oral Agents: A Three-Month, Outpatient, Parallel Comparative Trial (1093)  
Principal Investigator: Michael Davidson, M.D.
40. Protein XXXX Inhibitor-Diabetic Peripheral Arterial Disease (1097)  
Principal Investigator: Michael Davidson, M.D.
41. A Twenty-Four Week, Randomized, Double-Blind Study of the Effects of XXXXXX Versus XXXX and Placebo Administered Orally to Patients With Intermittent Claudication Secondary to Peripheral Arterial Disease (1104)  
Principal Investigator: Michael Davidson, M.D.
42. An Open-Label, Fixed Dose, Safety Trial of XXXXXX XXXXXX Tablets in Normal Volunteers (1244)  
Principal Investigator: Michael Davidson, M.D.
43. A Randomized, Double-Blind Controlled Evaluation of the Lipid-Altering Effects of XXXXXX XXXXXX XXXXXX and XXXXXX in Postmenopausal Women with Hypercholesterolemia (1251)  
Principal Investigator: Michael Davidson, M.D.
44. A Randomized, Double-Blind, Active and Placebo-Controlled, Parallel Group, Multicenter Study Assessing the Effect of XXXXXX XXXX Plus XXXX XXXXXX on Lipids in Postmenopausal Women (1256)  
Principal Investigator: Michael Davidson, M.D.
45. A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Compare the Efficacy and Safety of XXXXXX 0.4mg and 0.8mg Versus Placebo Once Saily in the Treatment of patients with Hypertriglyceridemia (1260)  
Principal Investigator: Michael Davidson, M.D.



46. Phase II Double-Blind, Parallel Design, Placebo and Active comparator-Controlled Trial of the Effects of XXXXXX on Lipoprotein Metabolism, Cardiovascular Reactivity and Cognitive Function in Postmenopausal Women **(1263)**  
Principal Investigator: Michael Davidson, M.D.
47. Multiple Dose Trial of Safety and Pharmacokinetics of XXXXXX Administered in Patients with Hypercholesterolemia on Background Statins **(1391)**  
Principal Investigator: Michael Davidson, M.D.
48. Evaluation of the Safety and Efficacy of XXXXXX: A Dose-Ranging Study **(1409)**  
Principal Investigator: Michael Davidson, M.D.
49. A Multi-Center, Randomized, Double-Blind, 2 Period, Complete Block, Crossover Study to Evaluate the Efficacy of XXXXXX and XXXXXX in Patients with Hypercholesterolemia **(1419)**  
Principal Investigator: Michael Davidson, M.D. **(North Shore)**
50. A 12 week Randomized double-blind Placebo-controlled Multicenter Trial to Evaluate the Efficacy and Safety of XXXXXX and XXXXXX in the Treatment of Subjects with Hypercholesterolemia **(1436)**  
Principal Investigator: Michael Davidson, M.D.
51. A Phase I Safety and Immunogenicity Study of the XXXX Vaccine in Healthy Adults **(1454)**  
Principal Investigator: Michael Davidson, M.D.
52. A Randomized Double-Blind Multicenter Trial to Compare the Short-term and Long-term Efficacy and Safety of XXXXXX, XXXXXX, and XXXX in the Treatment of Subjects with Hypercholesterolemia **(1567)**  
Principal Investigator: Michael Davidson, M.D.
53. A Multi-Center, Double-Blind, Randomized, Single-Dose, Placebo-Controlled Study to Investigate the Efficacy and Safety of 20.6mg and 10.3mg XXXXXX XXXXXX in Treating Heartburn Symptoms Following a provocative Meal **(1602)**  
Principal Investigator: Michael Davidson, M.D.
54. A Randomized, Double-Blind, Placebo Controlled Trial of XXXXXX Alone and in combination with XXXXXX in Patients with Primary Hypercholesterolemia **(2267)**  
Principal Investigator: Michael Davidson, M.D.
55. A 24-week Randomized Double-Blind Multicenter Multinational Trial to Evaluate the Efficacy and Safety of XXXXXX and XXXXXX in the Treatment of Subjects with Heterozygous Familial Hypercholesterolemia **(2295)**  
Principal Investigator: Michael Davidson, M.D.
56. Long-Term, Open Label, Safety and Tolerability Study of XXXXXX in Addition to XXXXXX in Subjects with Primary Hypercholesterolemia Who Have Previously Completed the 12-Week Double-Blind Study (Protocol Nos. P00679 or P00680) **(3512)**  
Principal Investigator: Michael Davidson, M.D.
57. Long-Term, Safety and Tolerability Study of XXXXXX or Placebo in Addition to XXXXXX in Subjects With Primary Hypercholesterolemia **(3585)**  
Principal Investigator: Michael Davidson, M.D.

58. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled and Open-Label Evaluation of the Safety and Efficacy of Dual Therapy with XXXXX Plus XXXXX When Compared to Either Therapy Alone in the Treatment of Patients with Simultaneous Hyperlipidemia and Hypertension (The AVALON Study) (3244)  
Principal Investigator: Michael Davidson, M.D.
59. A Randomized, Placebo Controlled, Double-Blind, Parallels Design Phase III Trial of the Efficacy and safety of XXXXXX in Male Patients with Mile to Moderate Erectile Dysfunction (3322)  
Principal Investigator: Michael Davidson, M.D.
60. A 6-Week, Open-Label, Dose-Comparison Study to Evaluate the Safety and Efficacy of XXXXXX Versus XXXXX, XXXXX, XXXXX, and XXXXX in Subjects With Hypercholesterolemia (3682)  
Principal Investigator: Michael Davidson, M.D.
61. Clinical Protocol for a Randomized, Double-Blind, Placebo-Controlled Study of XXXXX as Monotherapy in Patients with Primary Hypercholesterolemia (3616)  
Principal Investigator: Michael Davidson, M.D.
62. An Open-label, Randomized, Multi-center, Phase IIIb, Parallel Group Switching Study to Compare the Efficacy and Safety of Lipid Lowering Agents XXXXX and XXXXX with XXXXX in High Risk Subjects with Type IIa and IIb Hypercholesterolemia (4094)  
Principal Investigator: Michael Davidson, M.D.
63. Clinical Protocol for a Randomized, Double-Blind, Placebo-Controlled Study of XXXXX as Monotherapy in Patients with Primary Hypercholesterolemia (3636)  
Principal Investigator: Michael Davidson, M.D.
64. A Phase III, Double-Blind, Randomized, Placebo Controlled Study of XXXXX in Severely Obese Subjects (3696)  
Principal Investigator: Michael Davidson, M.D.
65. Double-Blind, Placebo-Controlled, Dose Ranging Trial To Evaluate The Efficacy Of XXXXX On Bone Mineral Density And Markers For Bone Turnover In Postmenopausal Women With Dyslipidemia And At Risk For Osteoporosis (3763)  
Principal Investigator: Michael Davidson, M.D.
66. A Single-Center, Randomized, Single-Blind, Placebo-Controlled, Phase II Study to Assess the Safety and Effects on HDL Cholesterol of XXXXX Vaccine in Subjects with Low HDL-Cholesterol (3755)  
Principal Investigator: Michael Davidson, M.D.
67. Measurement of the Glycemic Index of a Liquid Meal Replacement (4009)  
Principal Investigator: Michael Davidson, M.D.
68. A Multicenter, Double-Blind, Randomized, Placebo-and Active-Controlled, Parallel Study to Evaluate the Lipid Altering Efficacy and Safety of XXXXX in Patients with Metabolic Syndrome and Dyslipidemia (4011)  
Principal Investigator: Michael Davidson, M.D.

69. A Comparison of Treatment with XXXXX and XXXXX Coadministration Versus XXXXX in Attaining the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Coronary Heart Disease (CHD) or CHD Risk Equivalent Strata Low-Density Lipoprotein Cholesterol (LDL-C) Target Level (4203)  
Principal Investigator: Michael Davidson, M.D.
70. A Randomized, Double-Blind, Placebo-Controlled Study Of The Efficacy And Safety Of XXXXX Tablets In Patients With Primary Hypercholesterolemia (3713)  
Principal Investigator: Michael Davidson, M.D.
71. A Six Week, Randomized, Open-Label, Comparative Study to Evaluate the Efficacy and Safety of Rosuvastatin and Atorvastatin in the Treatment of Hypercholesterolemia in African American Subjects (4206)  
Principal Investigator: Michael Davidson, M.D.
72. A Multicenter, Double-Blind, Randomized, Parallel Group, 28 week Study to Evaluate the Efficacy and Safety of XXXXX and XXXXX Co-administration Versus XXXXX in Patients with Hypercholesterolemia (4223)  
Principal Investigator: Michael Davidson, M.D.
73. An Open Label Study of Topical XXXXX Gel Applied 2 Times per Week for 3 Weeks for Each Recurrence of Herpes Genitalis over 52 Weeks (4347)  
Principal Investigator: Michael Davidson, M.D.
74. An Eight-Week, Parallel Group, Double-blind, Randomized, placebo- and Active-controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Two Formulations of XXXXX, Each at Two Different Doses, in Obese Subjects (4317)  
Principal Investigator: Michael Davidson, M.D.
75. A Phase II, Randomized, Double Blind, Placebo-Controlled, Study of the Safety and Activity of XXXXX in Patients with Dyslipidemia (4628)  
Principal Investigator: Michael Davidson, M.D.
76. A Dose Range-Finding, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXXXX in Obese Subjects (4690)  
Principal Investigator: Michael Davidson, M.D.
77. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Parallel Group Phase III Study Measuring Effects on Intima Media Thickness: An Evaluation Of XXXXX (4523)  
Principal Investigator: Michael Davidson, M.D.
78. Efficacy of XXXXX as an Add-on to Simvastatin Therapy (4927)  
Principal Investigator: Michael Davidson, M.D.